PATENT
ATTORNEY DOCKET NO.: 54824-0006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 4,911,932		)
Granted:	March 27, 1990	)
		)
Patentees:	Charles E. CLUM *et al.*	)
		)
Assignee:	Johnson and Johnson Consumer Companies, Inc.	)
		)
FOR:	SKIN CARE COMPOSITIONS	)

Commissioner for Patents
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Randolph Building
401 Dulany Street
Alexandria, VA 22314

Date **April 5, 2006**

APPLICATION FOR EXTENSION OF PATENT TERM
PURSUANT TO 35 U.S.C. § 156

Sir:

Pursuant to Section 201(a) of the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156(a), Johnson & Johnson Consumer Companies, Inc. (formerly Johnson & Johnson Consumer Products, Inc.) hereby requests an extension of the patent term of United States Patent No. 4,911,932 (hereinafter variously referred to as "U.S. Patent No. 4,911,932" or "the '932 Patent).

Applicant, Johnson and Johnson Consumer Companies, Inc., a corporation created and existing under the Laws of the State of New Jersey, represents that it is the record owner of United States Patent No. 4,911,932, by reason of an assignment from the inventors thereof to Johnson & Johnson Babay Products Company recorded on February 11, 1985 at Reel/Frame 004370/0848; by merger of Pevrick Engineering Company, Inc., and Johnson & Johnson Baby Products Company, and change of name to Johnson & Johnson Orthopaedics, Inc. recorded

on March 16, 1988 at Reel/Frame 004898/0045; by assignment from Johnson & Johnson Orthopaedics, Inc. to Johnson & Johnson Consumer Products, Inc., recorded on March 16, 1988 at Reel/Frame 004898/0037, and by change of name to Johnson & Johnson Consumer Companies, Inc. recorded on March 17, 2006 (Reel/Frame not yet available), any and all of the above-named companies being referred to individually or collectively hereinafter as "JJCC." A copy of the Patent Assignment Abstract of Title printed from the U.S. Patent and Trademark Office Assignment website is included in **Exhibit 1** hereto, together with a copy of the recently recorded change of name to Johnson & Johnson Consumer Companies, Inc.

The Approved Product that forms the basis for this application was initially developed at JJCC (then designated as PEDIASTAT™), and is exclusively licensed by JJCC to Barrier Therapeutics, Inc. (hereinafter "Barrier") by an agreement dated May 6, 2002 (including an exclusive license under U.S. Patent No. 4,911,932). On June 21, 2002, ownership and responsibility for the management of IND 21,542 was also transferred from JJCC to Barrier. The undersigned registered practitioner, Donald J. Bird (Reg. No. 25,323), is counsel for the marketing applicant (Barrier), and has been authorized to act on behalf of the patent owner (JJCC) with respect to this Application and all correspondence pertaining thereto as set forth in section (15) below.

The following information is submitted in accordance with 35 U.S.C. § 156(d) and 37 C.F.R. § 1.710 *et seq.*, and follows the numerical sequence and format as set forth in 37 C.F.R. § 1.740(a):

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics.

The Approved Product is VUSION™ Ointment, which is comprised of a combination of three pharmacologically interacting active ingredients, being

miconazole nitrate (0.25%), zinc oxide (15%) and white petrolatum (81.35%), for topical use:

Miconazole nitrate has the chemical name:

1-[2,4-dichloro-β-{(2,4-dichlorobenzyl)oxy}phenethyl] imidazole mononitrate;

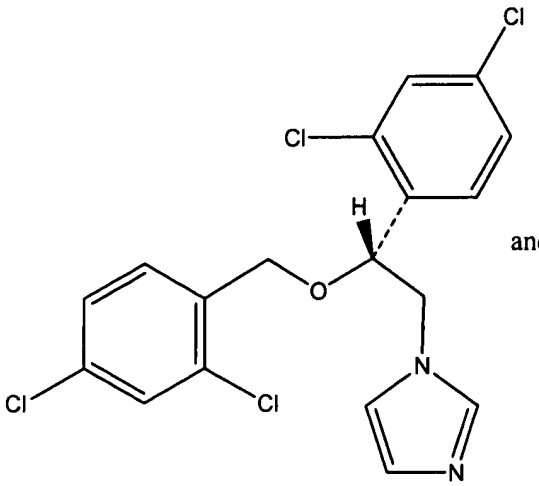
the empirical formula:

$C_{18}H_{14}Cl_4N_2O \cdot HNO_3$;

a molecular weight of:

479.15;

and the structural formula:



and enantiomer, HNO_3

Zinc oxide has the empirical formula:

ZnO;

and a molecular weight of:

81.39.

White petrolatum, which is obtained from petroleum and is wholly or nearly decolorized, is a purified mixture of semisolid saturated hydrocarbons having the general chemical formula C_nH_{2n+2}. The hydrocarbons consist mainly of branched and unbranched chains. White petrolatum contains butylated hydroxytoluene (BHT) as stabilizer.

Each gram of VUSION™ Ointment contains 2.5 mg of miconazole nitrate USP, 150 mg of zinc oxide USP, 81.35 mg of white petrolatum USP containing butylated hydroxytoluene, trihydroxystearin and Chemoderm® 1001/B fragrance.[1]

The miconazole nitrate component of the Approved Product has been shown to have *in vitro* activity against *Candida albicans*, an organism that is associated with diaper dermatitis. The activity of miconazole nitrate against *C albicans* is based on the inhibition of the ergosterol biosynthesis in the cell membrane. The accumulation of ergosterol precursors and toxic peroxides results in cytolysis of the cell. *Candida albicans* resistance to miconazole nitrate is unusual. The clinical significance of the *in vitro* activity of miconazole nitrate against *Candida albicans* in the setting of diaper dermatitis is unclear.

However, the pharmacological interaction of the active components of VUSION™ Ointment is effective in the stated indication for the adjunctive treatment of diaper dermatitis when complicated by candidiasis, as documented by microscopic evidence of pseudohyphae and/or budding yeasts, in immunocompetent pediatric patients 4 weeks and older.

(See the Approved Label attached as **Exhibit 2** with regard to the statements in this Section (1) and further description of the Approved Product).

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[1] Chemoderm® is a registered trademark of Firmenich Inc.

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred.

VUSION™ Ointment was subject to regulatory review under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(b)).

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred.

VUSION™ Ointment received permission for commercial marketing or use under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(b)) upon approval of NDA No. 21-026 on February 16, 2006, copy attached as **Exhibit 3**.

(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.

VUSION™ Ointment is comprised of three active ingredients, **miconazole nitrate, zinc oxide** and **white petrolatum**, as confirmed on page 1 of the approved label (**Exhibit 2**) and the Drug Detail printout for VUSION from Drugs@FDA (**Exhibit 4**).

Miconazole nitrate has previously been approved for commercial marketing as an active ingredient, as a single entity, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act under which the regulatory review period occurred, for use as a topical cream or ointment and as a vaginal suppository, as confirmed by the printouts from an active ingredient search of the Electronic Orange Book and Drugs@FDA attached as **Exhibit 5**).

Zinc oxide has **not** previously been approved for commercial marketing as an active ingredient, whether as a single entity or in combination with another active ingredient, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act under which the regulatory review period occurred, which is confirmed by the absence of any mention of zinc oxide as an active ingredient prior to the approval of VUSION™ Ointment on the attached printouts from an active ingredient search of the Electronic Orange Book and Drugs@FDA (**Exhibit 6**).

White petrolatum has **not** previously been approved for commercial marketing as an active ingredient, whether as a single entity or in combination with another active ingredient, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act under which the regulatory review period occurred, which is confirmed by the absence of any mention of white petrolatum as an active ingredient prior to the approval of VUSION™ Ointment on the attached printouts from an active ingredient search of the Electronic Orange Book and Drugs@FDA (**Exhibit 7**).

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted.

The product was approved on February 16, 2006, and the last day within the sixty day period permitted for submission of an application for patent term extension is April 17, 2006, which is subsequent to the date on which this Application has been submitted.

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration.

The complete identification of the patent for which an extension is being sought is as follows:

Inventors:	Charles E. Clum David M. Isaacson
U.S. Patent No.:	4,911,932
Earliest Filing Date:	January 18, 1984
Grant Date:	March 27, 1990
Expiration Date:	March 27, 2007

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings.

A full copy of U.S. Patent No. 4,911,932, for which extension is being sought, is attached as **Exhibit 8**.

(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.

No Certificate of Correction has been requested or issued with respect to the '932 Patent.

A copy of the maintenance fee statement showing timely payment of each maintenance fee when due is attached as **Exhibit 9**.

No disclaimer or reexamination certificate has been filed and/or issued for the '932 Patent.

(9) A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:

(i) The approved product, if the listed claims include any claim to the approved product.

(ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and

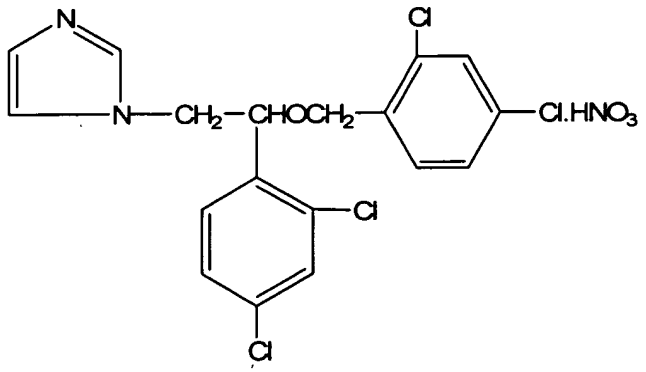
(iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product;

Claims 1-4 of U.S. Patent No. 4,911,932 read on the Approved Product as detailed below.

Patent Claims to the Approved Product:

Claims 1 and 2 of U.S. Patent No. 4,911,932 encompass (read on) the Approved Product as follows:

Claim 1. A skin care composition comprising as the active components (a) miconazole nitrate of the formula



and

(b) zinc oxide;

wherein the miconazole nitrate and zinc oxide are present in a ratio of from about 1:60 to about 1:333.

Claim 1 of U.S. Patent 4,911,932 reads on (encompasses) the Approved Product when considering that:

(i) A topical composition for the approved indication, which is the adjunctive treatment of diaper dermatitis when complicated by candidiasis, constitutes a "skin care composition."

(ii) The Approved Product is a composition comprising miconazole nitrate (of the same chemical structure depicted in this claim) and zinc oxide.

(iii) The composition of the Approved Product is comprised of 0.25% miconazole nitrate, 15% zinc oxide and 81.35% white petrolatum, which calculates to a miconazole nitrate : zinc oxide ratio of 0.0025 : 0.15 = 1:60, which is within the claimed range of from about 1:60 to about 1:333.

* * * * *

Claim 2. The composition of claim 1 wherein the miconazole nitrate and zinc oxide are present in a ratio of about 1:60.

Claim 2 is dependent on claim 1 and reads on (encompasses) the Approved Product for the reasons stated above, and more specifically:

(iii) The composition of the Approved Product is comprised of 0.25% miconazole nitrate, 15% zinc oxide and 81.35% white petrolatum, which calculates to a miconazole nitrate : zinc oxide ratio of 0.0025 : 0.15 = 1:60, which is the ratio set out in claim 2.

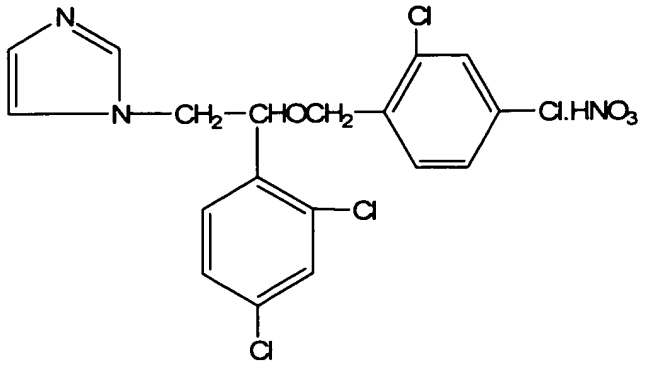
* * * * *

Patent Claims to the Method of Using the Approved Product:

Method claims 3 and 4 of U.S. Patent No. 4,911,932 encompass (read on) the Approved Product as follows:

Claim 3. A method for treating diaper rash comprising applying to the affected skin area a composition containing an antimicrobially effective amount of

(a) miconazole nitrate of the formula



and

(b) zinc oxide;

wherein the miconazole nitrate and zinc oxide are present in a ratio of from about 1:60 to about 1:333.

Claim 3 of U.S. Patent 4,911,932 reads on (encompasses) the Approved Product when considering that:

(i) the approved indication, which is the adjunctive treatment of diaper dermatitis when complicated by candidiasis, falls within the claimed method "for treating diaper rash.

(ii) The Approved Product is a composition comprising an antimicrobially effective amount of miconazole nitrate (of the same chemical structure depicted in this claim) and zinc oxide. See Example VII of the '932 Patent wherein the treatment using the claimed composition is directed toward inhibiting the growth of, *inter alia*, *Candida albicans*.

(iii) The composition of the Approved Product is comprised of 0.25% miconazole nitrate, 15% zinc oxide and 81.35% white petrolatum, which calculates to a miconazole nitrate : zinc

oxide ratio of 0.0025 : 0.15 = 1:60, which is encompassed by the claimed range of from about 1:60 to about 1:333.

* * * * *

Claim 4. The method of claim 3 wherein the miconazole nitrate and zinc oxide are present in a ratio of about 1:60.

Claim 4 is dependent on claim 3 and reads on (encompasses) the Approved Product for the reasons stated above, and more specifically:

(iii) The composition of the Approved Product is comprised of 0.25% miconazole nitrate, 15% zinc oxide and 81.35% white petrolatum, which calculates to a miconazole nitrate : zinc oxide ratio of 0.0025 : 0.15 = 1:60, which is the ratio set out in claim 4.

* * * * *

Patent Claims to the Method of Manufacturing the Approved Product:

No claims of U.S. Patent No. 4,911,932 are directed toward a method of manufacturing the Approved Product.

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product:

(A) The effective date of the investigational new drug (IND) application and the IND number;

The IND application for the Approved Product (0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum ointment) was submitted by JJCC on February 4, 1983, but placed on clinical hold March 3, 1983 due to safety concerns. The safety concerns were addressed and the IND was released from clinical hold on September 21, 1983. Therefore, IND 21,542 has an effective date of **September 21, 1983**.

On May 6, 2002, JJCC entered into an Agreement with Barrier granting Barrier the exclusive right to develop and commercialize the Approved Product, including an exclusive license under U.S. Patent 4,911,932. Effective June 21, 2002, JJCC transferred sole ownership and responsibility for the management of IND 21,542 to Barrier, and Barrier accepted the ownership and the responsibility for management of the IND. The FDA was notified of this Transfer of Ownership by letters dated June 21, 2002 from JJCC and Barrier (copies attached as **Exhibit 10**.

Under these circumstances, the "regulatory review period" under 35 U.S.C. § 156(g)(1) began on **September 21, 1983**, the effective date of IND 21,542.

(B) The date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number; and

NDA No. 21-026 for VUSION™ Ointment was initially submitted to the FDA on August 24, 1998 by JJCC, and was received by the FDA on August 24,

1998 and assigned NDA No. 21-026. This establishes August 24, 1998 as the initial submission date of the NDA for the Approved Product for purposes of 35 U.S.C. 156(g)(1). See confirmation of the NDA filing and receipt date on page 1 of the FDA Approval Letter of **Exhibit 3**.

(C) The date on which the NDA was approved or the Product License issued.

The NDA was approved by the FDA approval letter sent February 16, 2006, setting the effective date of the approval as the February 16, 2006 date of the letter. A copy of this FDA approval letter is attached as **Exhibit 3.** This establishes the end of the "regulatory review period" under 35 U.S.C. 156(g)(1) as **February 16, 2006**.

(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

The significant activities undertaken by the marketing applicant with respect to the Approved Product during the applicable regulatory review period commenced with the effective date of Investigational New Drug Application IND 21,542 on September 21, 1983 and continued through the testing period to the filing of NDA 21-026, and thereafter through the approval period to the date of the FDA approval letter on February 16, 2006. A Chronological Listing of Significant Activities during the regulatory review period for VUSION™ Ointment, is attached as **Exhibit 11**, the contents of which are incorporated herein by reference as providing a brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the Approved Product.

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined.

Statement That The Patent Is Eligible For Extension

A patent is eligible for extension if the following statutory criteria of 35 U.S.C. § 156 are met:

> **§ 156 Extension of patent term**
>
> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if –
>
> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
>
> (2) the term of the patent has never been extended under subsection (e)(1) of this section;
>
> (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
>
> (5) (A) ... the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;
>
> * * *
>
> (c)(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.
>
> * * *
>
> (f) For purposes of this section:
>
> (1) The term "product" means:

(A) A drug product.

* * *

(2) The term "drug product" means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) ... including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

Applicant is of the opinion that U.S. Patent No. 4,911,932 is eligible for extension under 35 U.S.C. § 156 because it satisfies all of the requirements for such extension as follows:

(1) 35 U.S.C. 156(a)

U.S. Patent No. 4,911,932 claims the Approved Product, as detailed in section (9) above.

(2) 35 U.S.C. 156(a)(1)

U.S. Patent No. 4,911,932 granted March 27, 1990 on an earliest filed U.S. application filed on January 18, 1984 and there are no terminal disclaimers. As such, the patent expires on March 27, 2007, being 17 years from grant. This application, therefore, has been submitted before the expiration of the patent term.

(3) 35 U.S.C. 156(a)(2)

The term of this patent has never been extended.

(4) 35 U.S.C. 156(a)(3)

This application is being submitted by JJCC as the owner of record of U.S. Patent No. 4,911,932 (through an assignment from the inventors and subsequent recorded assignments and change of name as detailed on pages 1-2 above), in accordance with the requirement of 35 U.S.C. 156(d) and rules of the U.S. Patent and Trademark Office.

(5) 35 U.S.C. 156(a)(4)

As evidenced by the February 16, 2006 approval letter from the FDA (**Exhibit 3**), VUSION™ Ointment, was subject to a regulatory review period under Section 505(b) of the Federal Food, Drug, and Cosmetic Act before its commercial marketing or use.

(6) 35 U.S.C. 156(a)(5)(A)

VUSION™ Ointment is comprised of three active ingredients, miconazole nitrate, zinc oxide and white petrolatum, as confirmed on page 1 of the Approved Label (**Exhibit 2**) and the Drug Detail printout for VUSION from Drugs@FDA (**Exhibit 4**).

The permission for commercial marketing or use of VUSION™ Ointment is the first permitted commercial marketing of **zinc oxide** as an active ingredient, whether as a single entity or in combination with another active ingredient, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act under which the regulatory review period occurred, which is confirmed by the absence of any mention of zinc oxide as an active ingredient prior to the approval of VUSION™ Ointment on the attached printouts from an active ingredient search of the Electronic Orange Book and Drugs@FDA (**Exhibit 6**).[2]

The permission for commercial marketing or use of VUSION™ Ointment is the first permitted commercial marketing of **white petrolatum** as an active ingredient, whether as a single entity or in combination with another active ingredient, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act under which the

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[2] The products searched in the Electronic Orange Book were prescription human drugs currently approved for sale in the United States. The products searched in Drugs@FDA were prescription and over-the-counter human drugs approved via a New Drug Application and currently approved for sale in the United States.

regulatory review period occurred, which is confirmed by the absence of any mention of white petrolatum as an active ingredient prior to the approval of VUSION™ Ointment on the attached printouts from an active ingredient search of the Electronic Orange Book and Drugs@FDA (**Exhibit 7**).

Miconazole nitrate has previously received permission for commercial marketing as an active ingredient, as a single entity, under Section 505(b) of the Federal Food, Drug and Cosmetic Act under which the regulatory review period occurred, as confirmed by the printouts from an active ingredient search of the Electronic Orange Book and Drugs@FDA attached as **Exhibit 5**).

In view of the above, the permission for commercial marketing or use of the product VUSION™ Ointment, after such regulatory review period, meets the statutory criteria of section 156(a)(5)(A). Applicant is aware of the Federal Circuit decision of *Arnold Partnership v. Dudas*, 362 F.3d 1338, 70 U.S.P.Q.2d 1311 (Fed. Cir. 2004) regarding combination products, but the approval of VUSION™ Ointment is distinguished therefrom inasmuch as two of the three active ingredients have not previously received permission for commercial marketing as an active ingredient, whether as a single entity or in combination with another active ingredient, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act under which the regulatory review period occurred, prior to the approval of VUSION™ Ointment.

Moreover, VUSION™ Ointment is a combination of pharmacologically interacting active ingredients, as established by the decision of the Board of Patent Appeals and Interferences in Application No. 06/700,165, holding that a synergistic effect had been demonstrated between at least the miconazole nitrate and zinc oxide components of the Approved Product, which decision lead to the grant

of the '932 Patent. A copy of this decision in Appeal No. 87-2039, rendered on September 15, 1989, is attached as **Exhibit 12**. In this regard, attention is drawn to MPEP § 2751, under the heading "First Permitted Marketing or Use," which considers a combination of active ingredients "shown to have a synergistic effect or have pharmacological interaction" to be "a single active ingredient made of two active ingredients."[3]

(7) 35 U.S.C. 156(c)(4)

No other patent has been extended for the same regulatory review period for the product VUSION™ Ointment.

Statement as to Length of Extension Claimed

The term of U.S. Patent No. 4,911,932 should be extended by **1827 days**, from March 27, 2007 to **March 27, 2012**. In accordance with the implementing regulations of 37 C.F.R. 1.175 with respect to patent term extensions for a human drug product, the term extension of U.S. Patent No. 4,911,932 based on the regulatory review for VUSION™ Ointment was determined as follows:

> **Sec. 1.775 Calculation of patent term extension for a human drug, antibiotic drug or human biological product.**
>
> **(a) If a determination is made pursuant to Sec. 1.750 that a patent for a human drug, antibiotic drug or human biological product is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (Sec. 1.321).**

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[3] MPEP at page 2700-32; 8th Edition, August 2001, Latest Revision October 2005, from the US PTO current website.

U.S. Patent 4,911,932 issued on March 27, 1990, from an earliest filed U.S. application filed on January 18, 1984. Pursuant to 35 U.S.C. 154(c), this patent is entitled to an original term of 17 years from its grant on March 27, 1990, which provides an original expiration date of **March 27, 2007**.

> **(b) The term of the patent for a human drug, antibiotic drug or human biological product will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.**
>
> **(c) The length of the regulatory review period for a human drug, antibiotic drug or human biological product will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(1)(B), it is the sum of--**
>
> **(1) The number of days in the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act became effective for the approved product and ending on the date the application was initially submitted for such product under those sections or under section 351 of the Public Health Service Act; and**
>
> **(2) The number of days in the period beginning on the date the application was initially submitted for the approved product under section 351 of the Public Health Service Act, subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.**

The number of days in the IND testing period of paragraph (c)(1) extends from the effective date of IND 21,542 on September 21, 1983 to the filing of NDA 21-026 on August 24, 1998, being **5452 days**.

The number of days in the NDA approval period of paragraph (c)(2) extends from the filing of NDA 21-026 on August 24, 1998 to the date of approval of NDA 21-026 on February 16, 2006, being **2734 days**.

The regulatory review period is the sum of the periods of paragraphs (c)(1) and (c)(2), being **8186 days**.

> **(d) The term of the patent as extended for a human drug, antibiotic drug or human biological product will be determined by--**

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction;

With respect to paragraph (d)(1)(i), **2370 days** of the periods of paragraphs (c)(1) and (c)(2) were before the March 27, 1990 date on which original U.S. Patent 4,911,932 issued.

With respect to paragraph (d)(1)(ii), 35 U.S.C. 156(d)(2)(B) provides that if a petition is submitted to the Secretary not later than 180 days after publication of the determination of the applicable regulatory review period, upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making this determination shall notify the Director of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing, and shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Director

of any revision of the determination and shall publish any such revision in the Federal Register. There has been no such petition or determination by the Secretary, and thus the number of days under (d)(1)(ii) is **0 days**.

With respect to paragraph (d)(1)(iii), one-half of the number of days remaining in the period defined by paragraph (c)(1) after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) is one-half of (5455-2379-0=5455) days, which is **1536 days** (ignoring the half day).

Subtracting from the regulatory review period of 8185 days as determined above pursuant to section 1.175(c) the number of days determined above with respect to paragraphs (d)(1)(i), (ii) and (iii), the term of patent extension is **8186 days** minus **2380 days** minus **0 days** minus **1536 days** for a sum total of **4270 days**.

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

The original term of U.S. Patent No. 4,911,932 is March 27, 2007 and is not shortened by terminal disclaimer. Adding the 4270 days determined in paragraph (d)(1) to the original term of the patent results in an extended term to **December 4, 2018.**

(3) By adding 14 years to the date of approval of the application under section 351 of the Public Health Service Act, or subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act;

Adding 14 years to the February 16, 2006 date of the approval of the NDA results in the date **February 16, 2020.**

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

The earlier of December 4, 2018 and February 16, 2020 is **December 4, 2018.**

(5) If the original patent was issued after September 24, 1984,
(i) By adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and
(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

The original patent issued after September 24, 1984. Adding 5 years to the original expiration date of the patent (there was no terminal disclaimer) of March 27, 2007 gives a date of **March 27, 2012**. The earlier of March 27, 2012 and December 4, 2018 is **March 27, 2012**.

(6) If the original patent was issued before September 24, 1984, and
(i) If no request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act before September 24, 1984, by--
(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and
(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or
(ii) If a request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, or Cosmetic Act before September 24, 1984 and the commercial marketing or use of the product was not approved before September 24, 1984, by--
(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and
(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

Since U.S. Patent 4,911,932 issued after September 24, 1984, no further adjustment to the extended term of **March 27, 2012** is required.

Thus, as calculated above, the term of U.S. Patent No. 4,911,932 is eligible for a **1827 day extension to March 27, 2012**.

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (see § 1.765).

Applicant acknowledges a duty to disclose to the Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to any determination of entitlement to the extension sought.

(14) The prescribed fee for receiving and acting upon the application for extension (see § 1.20(j)).

As noted in the letter of transmittal submitted with this application, the Patent and Trademark Office is authorized to charge the filing fee of $1,120.00 and any additional fees which may be required by this or any other related paper, or to credit any overpayment to Deposit Account No. 50-0310.

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed.

Please address all inquiries and correspondence relating to this application for patent term extension to the following registered practitioner, who is counsel for the marketing applicant and authorized to act on behalf of the patent owner with respect to this Application and all correspondence pertaining hereto (Authorization attached as **Exhibit 13**):

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Respectfully Submitted,
Morgan, Lewis & Bockius LLP

Date: April 5, 2006 By: _____

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